



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 14, 2020

Sara Seltzer
Registration Specialist
Diversey, Inc.
2415 Cascade Pointe Boulevard
Charlotte, NC 28208

Subject: Label Amendment – Emerging Viral Pathogens Claim
Product Name: Phato 1:64 Disinfectant Cleaner
EPA Registration Number: 70627-62
Application Date: March 11, 2020
Decision Number: 560811

Dear Ms. Seltzer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

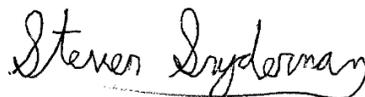
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, or enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus (ATCC VR-782) and Rhinovirus Type 37 (ATCC VR-1147) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

(Note to Agency: Text appearing in parenthesis is done to show optional text.)



PHATO 1:64 DISINFECTANT CLEANER

(ONE STEP DISINFECTANT CLEANER AND DEODORANT)
(ALL-IN-ONE) (MULTI-SURFACE) ((ONE-STEP) DISINFECTANT)
(SANITIZER) • (CLEANER) • (*VIRUCIDAL) • (BACTERICIDAL)
(DEODORIZER) (ODOR COUNTERACTANT) (ODOR NEUTRALIZER)
(NON-DULLING TO FLOORS (FLOOR FINISHES)) • (CONCENTRATE) • (READY-TO-DISPENSE (RTD))
(CLEANS, DISINFECTS & DEODORIZES) (SANITIZES)
(MEETS OSHA BLOODBORNE PATHOGEN STANDARD FOR *HBV & *HIV)

(Restroom) (&) (Bathroom) (Disinfectant Cleaner) (Hospital Disinfectant Cleaner) (Multi-Surface Disinfectant Cleaner)
(Cleans, Deodorizes and Brightens in One Step) (Cleans Grout)
(Cleans all hard, non-porous water washable surfaces!) (Degreaser)
(Use Daily to Prevent the Build up of Dirt and Grime.)

(Fragrance Free Formula) (Unscented) (Outdoor Fresh)
(Fresh [Lemon] [Spring Fresh] [Citrus] Scent)

(For (Hospital,) (Health Care,) (Industrial) & (Institutional) Use)

ACTIVE INGREDIENT:	
Hydrogen Peroxide.....	4.25%
OTHER INGREDIENTS:	<u>95.75%</u>
TOTAL:	100.00%

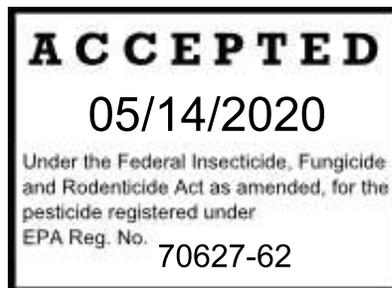
KEEP OUT OF REACH OF CHILDREN CAUTION

See additional precautionary statements on back (side) (left) (right) (panel) (of) (label) (below).

[See reference sheet (enclosed in each case) for (a complete list of pathogenic organisms) (additional features, claims, direction for use) (claimed for this product) (eliminated by this product).]

(MSDS Ref. No. xxxxxxxxxx)

Net Contents:



(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(MARKETING CLAIMS): (Note to EPA - This text will only appear on the appropriate container.)

ACCUMIX®-CONTAINERS (32 oz. (1 qt.) container) - ACCUMIX®. (Remove [Loosen] cap). Squeeze. (Squeeze bottle.) Measure. (Measure amount). Pour. (Pour contents). (Designed) For use with 5 gallon Buddy Jugs™ (the BIG BUDDY™ [ACCUTAINER™] System). This product can also be diluted into pre-cleaned and properly labeled 5-gallon BUDDY JUG™ (ACCUTAINERS™) (Dispensing Containers) for dispensing as needed.

SOLUTIONS CENTER™ DISPENSING SYSTEMS (64 oz. (2 qt.) containers) - For use with (Diversey) (JOHNSONDIVERSEY™) (SOLUTIONS CENTER™) Brand Dispensing Equipment. Dispense with cold water. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. Disinfectant Cleaning With The Convenience Of (SOLUTIONS CENTER™). ((SOLUTIONS CENTER™) ((This) packaging) offers) Reduced Exposure To Concentrate Due To Closed Transfer System. Solutions To Go!

J-FILL™ DISPENSING SYSTEMS (84.5 oz. (2.5 L) containers) - For use with (Diversey) (JOHNSONDIVERSEY™) (J-FILL™) Brand Dispensing Equipment. Dispense with cold water. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. Disinfectant Cleaning With The Convenience Of J-FILL™. ((J-FILL™) ((This) packaging) offers) Reduced (Reduces) Exposure To Concentrate Due To Closed Transfer System. Solutions To Go!

RTD™ DISPENSING SYSTEMS (1.5 L & 5 L containers) - RTD. Very Simple. Very Smart. Out of the box. Ready-To-Dispense. Dispense with cold water. Provides accuracy. No chemical connections, sealed bottle. Proven dilution control concentrate.

OUTPOST™ (SINGLE SOLUTION™) DISPENSING SYSTEMS (2 L containers) (3 L containers) - For use with (Diversey) (BUTCHER™) (RAMSEY™) (OUTPOST™) (SINGLE SOLUTION™) Brand Dispensing Equipment. Dispense with cold water. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. ((OUTPOST™) (SINGLE SOLUTION™) ((This) packaging) offers) Reduced Exposure To Concentrate Due To Closed Transfer System.

PRACTICAL SOLUTIONS™ DISPENSING SYSTEMS (1 gal. containers) - For use with (Diversey) (BUTCHER™) (RAMSEY™) (PRACTICAL SOLUTIONS™) Brand Dispensing Equipment. Dispense with cold water. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. ((PRACTICAL SOLUTIONS™) ((This) packaging) offers) Reduced Exposure To Concentrate Due To Closed Transfer System.

COMMAND CENTER™ DISPENSING SYSTEMS (1.5 gal. containers) - For use with (Diversey) (BUTCHER™) (COMMAND CENTER™) Brand Dispensing Equipment. Dispense with cold water. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. ((COMMAND CENTER™) ((This) packaging) offers) Reduced Exposure To Concentrate Due To Closed Transfer System.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(FEATURES, CLAIMS & USES:)

(General Uses)

This product is a one-step (hospital-use) (hospital-grade) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (and) (deodorizing) (of) hard, non-porous inanimate surfaces. It cleans quickly by removing dirt, grime, body oils and other common soils found in hospitals, nursing homes, (acute) (and) (long-term) (assisted living) care facilities, office buildings, schools and colleges (universities), (day care centers), (medical) (dental) offices, funeral homes, transportation facilities, train (depots) (stations), bus (depots) (stations), airports, cruise ships, casinos, retail facilities, correctional facilities, athletic facilities, playgrounds, (gym) locker rooms, health clubs, exercise equipment, veterinary clinics, pet shops, (equine farms), (poultry) (barns) (farms) (hatcheries), animal life science laboratories, hotels, motels, public areas and restrooms, foodservice establishments (restaurants) and federally inspected meat and poultry establishments (food [processing] [beverage] [brewing] plants), (dairies) (dairy farms), (warehouses) ([industrial (and)] (commercial) buildings.

It is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces: vinyl, painted surfaces, plastic (surfaces), glass, mirrors, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, countertops, telephones, fixtures, athletic equipment, (exercise) (fitness) equipment, glazed tile, toilets, urinals, sinks, sink basins, faucets, tubs, shower rooms and locker room areas – any hard, non-porous washable (non-food contact) surface where disinfection is required. This product's (non-dulling) (advanced) (deep-cleaning) formula eliminates the time and labor normally required for rinsing. Do not use on glasses, dishes and utensils.

((Bathroom) (Restroom) (Bowl) Disinfectant Cleaner:)

This product is a (concentrated) (bowl and) (bathroom) (restroom) cleaner which cleans, disinfects and deodorizes in one easy step. It cleans, disinfects and deodorizes mirrors, glass, toilet bowls, urinals, rims, sinks, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel, and all hard non-porous, washable surfaces found in the bathroom (restroom) (in the presence of organic soil).

This product reduces odor-causing bacteria leaving (bathrooms) (restrooms) smelling clean and fresh. Use where odors are a problem. It cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its non-abrasive formula is designed for use (Use it daily) on ([hard, non-porous inanimate] (bathroom) (restroom) surfaces): mirrors, glazed ceramic (bathroom) (restroom) tile, glazed porcelain, chrome, stainless steel and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

This product cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its non-abrasive formula is designed for use on (restroom surfaces:) glazed ceramic (restroom) tile, glazed porcelain, chrome, stainless steel and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(Hospitals/Health Care Facilities:)

This product is a one-step (hospital-use) (hospital grade) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (of) hard, non-porous environmental surfaces. This product cleans quickly by removing dirt, grime, food residue, body oils, dead skin, blood and other organic matter commonly found in hospitals (acute) (and) (long-term) (nursing homes) (assisted living) care facilities (and) (in health care facilities) (on medical surfaces). It (also) reduces odor-causing bacteria, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

This product cleans, disinfects and deodorizes (hard, non-porous environmental hospital (medical) surfaces) in one step (with no rinsing required). Its non-abrasive formula is designed for use on (Use daily on) (the following) hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, countertops, telephones, fixtures, glazed tile, toilets, urinals, sinks found in (health care facilities [hospitals],) patient rooms, operating rooms, ICU areas, shower rooms, and locker rooms. (It can also be used to pre-clean and disinfect hospital items: wheelchairs, [hospital] [patient] bed rails and linings, wash basins, bed pans, and medical equipment surfaces.) - any washable hard, nonporous non-food contact surface (where disinfection is required). Do not use on glasses, dishes and utensils.

(Food Service/Food Processing:)

This product cleans by removing dirt, grime and food soils in food preparation and processing areas. Its non-abrasive formula will not harm (scratch) surfaces. It cleans, disinfects and reduces odor-causing bacteria leaving surfaces smelling clean and fresh. Use where odors are a problem. (This product) deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, (floor) drains and other areas which are prone to odors caused by microorganisms in foodservice establishments (restaurants) and federally inspected meat and poultry establishments (food [processing] [Beverage] [Brewing] plants), (Dairies) (Dairy farms).

Its non-abrasive formula is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces): vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, aluminum, stainless steel, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, countertops, fixtures, glazed tile, toilets, (toilet bowls), urinals, sinks found in food establishments, (restaurants), (commercial kitchens) & restrooms. Do not use on glasses, dishes and utensils.

(Animal Housing Facilities:)

This product cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing facilities, livestock, swine or poultry facilities, grooming facilities, farms, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) reduces odor-causing bacteria leaving surfaces smelling clean and fresh.

This product cleans, disinfects and deodorizes (hard, non-porous inanimate surfaces) in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) hard, non-porous surfaces: plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, sealed concrete, laminated surfaces (associated with floors, walls, countertops, cages, kennels, animal equipment) found in (barns, pens and stalls) animal housing facilities.

(Refill)

(To Refill Concentrate From Large Containers Into Smaller Containers:)

This product may be used to fill and refill clean, properly labeled containers for dilution elsewhere within your facility. Make sure the small container has been cleaned, dried and properly labeled. Also make sure other items (funnels or hand pumps) are properly cleaned and dried. To refill, simply pour (or pump product) from the larger container directly into the smaller one, being careful not to spill any product. Keep both containers sealed when not in use.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(CLAIMS:)

When used as directed, this product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic-resistant bacteria, and *viruses). At a 1:64 dilution (2 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 10 minute contact time, unless otherwise noted, this product kills the following on hard non-porous inanimate surfaces:

Bacteria (Bactericidal Activity):

Pseudomonas aeruginosa, (ATCC 15442)

Salmonella enterica, (ATCC 10708)

formerly known as *Salmonella choleraesuis*

Staphylococcus aureus, (ATCC 6538)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Staphylococcus aureus, (Methicillin Resistant *Staphylococcus aureus* [MRSA]) (ATCC 33591)

Staphylococcus aureus, (Community Associated - Methicillin Resistant *Staphylococcus aureus* [CA-MRSA]) (Clinical Isolate 08005)(Genotype USA400)

Enterococcus faecium, (Resistant to Vancomycin [VRE]) (ATCC 51559)

Staphylococcus aureus, (Community Associated - Methicillin Resistant *Staphylococcus aureus* [CA-MRSA]) (Clinical Isolate 08001) (Genotype USA300)

At a 1:64 dilution (2 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 5 minute contact time, unless otherwise noted, this product kills the following on hard non-porous inanimate surfaces:

***Viruses (*Virucidal Activity):**

*Adenovirus type 8, (ATCC VR-1368, Strain Trim)

*Herpes Simplex Virus Type 2, (VR-734)

*Human Coronavirus, (VR-740)

*Influenza Virus Type A₂ (Hong Kong), (VR-544)

*Norovirus (Feline Calicivirus as the surrogate), (VR-782)

*Parainfluenza Virus Type 3, (VR-93)

*Poliovirus Type 1, (ATCC VR-1000)

*Respiratory Syncytial Virus, (VR-26)

*Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)

*Rotavirus, (Strain WA)

*Vaccinia Virus (smallpox vaccine virus), (ATCC VR-119)

Kills *Hepatitis B Virus (HBV) & *Hepatitis C Virus (HCV) when used as directed on hard, non-porous inanimate surfaces with a 5 minute contact time.

Kills *HIV-1 (Human Immunodeficiency Virus Type 1) (AIDS virus) (HTLV-III_B) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Kills *Influenza A Virus (H1N1) (ATCC VR-1469, Strain A/PR/8/34) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

(*Veterinary Viruses:)

*Avian Influenza Virus A, (H3N2) (ATCC VR-2072)

Sanitizing: When used as a non-food contact sanitizer at a 1:128 dilution (1 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load, this product reduces the following bacteria by 99.9% with a 3 minute contact time on hard non-porous inanimate surfaces:

Staphylococcus aureus (ATCC 6538)

Klebsiella pneumoniae (ATCC 4352)

Escherichia coli (ATCC 11229)

Enterococcus faecalis (ATCC 29212)

Listeria monocytogenes (ATCC 19111)

Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica, (ATCC 10708)

(formerly known as *Salmonella choleraesuis*)

Bactericidal Stability of Use-Solution - Tests show this product as a disinfectant, when diluted at 1:64 dilution (2 oz. of product per gallon of water) in 200 ppm hard water, in the presence of 5% serum, remains effective against *Staphylococcus aureus*, *Salmonella enterica* (formerly known as *Salmonella choleraesuis*) and *Pseudomonas aeruginosa* for up to 10 (- 90) days in storage as long as the bottle remains sealed. If the use-solution becomes visibly dirty or contaminated, it must be discarded and a fresh product prepared. Always use clean, dry containers when diluting this product. Treated surfaces must remain wet for 10 minutes.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Malodor(s) (Activity) (Odor) (Counteractancy) - reduces odors and odor-causing bacteria on hard, nonporous surfaces, in restroom areas behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors), (when used as directed at a 1:64 dilution (2 oz. of product per gallon of water)), (or) (when used as directed at a 1:64 - 1:128 dilution (1 - 2 oz. per gallon of water)), in the presence of 200 ppm hard water and a 3 minute contact time.

(Emerging Pathogens Claims)

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA- Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped Viruses	Feline Calicivirus
Large, Non-Enveloped Viruses	Feline Calicivirus
Small, Non-Enveloped Viruses	Feline Calicivirus Rhinovirus Type 37 (ATCC VR-1147)

Acceptable claim language:

(PHATO 1-64 Disinfectant Cleaner) (Approved EPA Alternate Brand Name) (This product) has demonstrated effectiveness against viruses similar to [insert name of emerging virus] on hard, non-porous surfaces. Therefore, (PHATO 1-64 Disinfectant Cleaner) (Approved EPA Alternate Brand Name) (This product) can be used against [insert name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus or Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the (CDC or OIE) website at [insert pathogen- specific website address] for additional information.

[Insert name of illness / outbreak] is caused by [insert name of emerging virus]. (PHATO 1-64 Disinfectant Cleaner) (Approved EPA Alternate Brand Name) (This product) kills similar viruses and therefore can be used against [insert name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus or Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the (CDC or OIE) website at [insert pathogen-specific website address] for additional information.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(Modes of Application:)

This product can be applied by mop, sponge, cloth, paper towel, disposable wipe, (hand pump) coarse trigger sprayer, or auto-scrubber. Change cloth, sponges or towels frequently to avoid redeposition of soil.

(Note to reviewer: This statement is required only on product labels that include semi-critical devices as defined by FDA.) (This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

Not recommended for use on copper, brass, granite, marble or zinc.

To Prepare Use Solution: Add the product at 2 oz. per gallon of water (1:64).

(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on the single dilution containers.)

(GENERAL DISPENSER INSTRUCTIONS) [These instructions may be substituted for any dispensing device to prepare the use solution]: (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is properly inserted into dispenser, follow dispenser use instructions to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

SOLUTIONS CENTER™ DISPENSING SYSTEMS (64 oz. containers) – (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, (squeeze the handle) (or) (press the button) to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

J-FILL™ DISPENSING SYSTEMS (84.5 oz. containers) – (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, (squeeze the handle) (or) (press the button) to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

OUTPOST™ (SINGLE SOLUTION™) DISPENSING SYSTEMS (2 L containers) (3 L containers) – (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place turn the knob to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

PRACTICAL SOLUTIONS™ DISPENSING SYSTEMS (1 gal. containers) – (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, press the button to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

COMMAND CENTER™ DISPENSING SYSTEMS (1.5 gal. containers) – (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, press the button to dispense a 1:64 solution into a bucket, bottle, scrubber or other container.

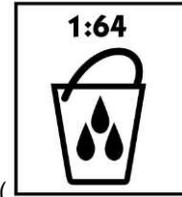
(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(For Multiple Dilution Dispensers)

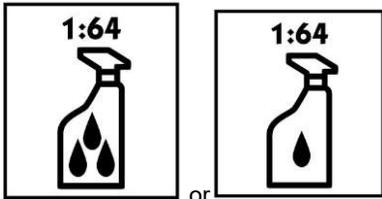
(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on multiple dilution containers.)

(GENERAL DISPENSER INSTRUCTIONS) [These instructions may be substituted for any dispensing device to prepare the use solution]: (Remove cap and) Insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is properly inserted into dispenser, follow dispenser use instructions to dispense a 1:64 to 1:256 solution into a bucket, bottle, scrubber or other container.

RTD™ SYSTEMS (1.5 or 5 L containers) - Using the RTD unit, dispense product into a (trigger sprayer), (auto scrubber,) (or) bucket. Turn off water to connect unit. Attach to water source. Rotate control knob to fill bottle (or bucket). Squeeze handle to dispense a 1:64 to 1:256 solution into a bottle (bucket) (or other container). See device instruction manual for more information.

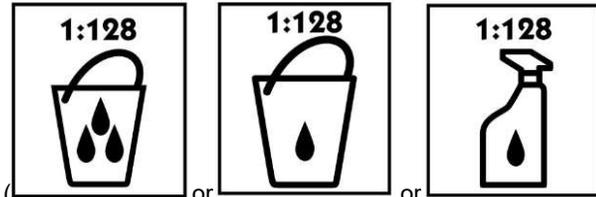


For Disinfection (and) (Cleaning) and Deodorizing(Deodorization) set the control knob to the (



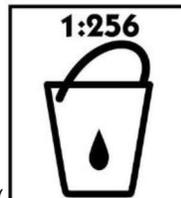
) setting which provides 2 oz. of product per gallon of water dilution (1:64).

For Non-Food Contact Sanitization, (and) (or) (Cleaning) and Deodorizing (Deodorization) set the control knob to the



(

) setting which provides 1 oz. of product per gallon of water dilution (1:128).



For Use as a Cleaner/Degreaser set the control knob to the (

) setting which provides ½ oz. of product per gallon of water dilution (1:256).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

For Use as a (Daily) (One-Step) Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution to hard, non-porous inanimate surfaces.
3. To disinfect, all surfaces must remain wet for ten (10) minutes.
4. Wipe surfaces (and let air dry).

Note - Rinsing is not necessary unless floors are to be coated with finish or restorer. When cleaning floors position wet-floor signs around area to be cleaned. Floors will be slippery when wet or contaminated with foreign materials. Promptly clean up spills and foreign materials. Do not use on glassware, utensils, or dishes.

For Use as (Daily) Bathroom (Restroom) (One-Step) Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution by (hand pump) coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 - 8 inches from surface; making sure to wet surfaces thoroughly.
3. All surfaces must remain wet for ten (10) minutes.
4. Wipe surfaces (and let air dry).

Note - Rinsing is not necessary unless floors are to be coated with finish or restorer. When cleaning floors position wet-floor signs around area to be cleaned. Floors will be slippery when wet or contaminated with foreign materials.

For Use To Clean and Disinfect Shower Rooms, Locker Rooms and Other Large, Open Areas with Floor Drains:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution to floors, walls and ceilings making sure not to over spray. To disinfect, all surfaces must remain wet for ten (10) minutes.
3. Scrub using a deck brush or other coarse material as necessary.
4. Rinse surfaces thoroughly and let air dry.

Note - When cleaning floors position wet-floor signs around area to be cleaned. Floors will be slippery when wet or contaminated with foreign materials.

For use as a *Virucide:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution until thoroughly wet.
3. Let stand for five (5) minutes.
4. Wipe surfaces (and let air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

***This product kills HBV, HCV and HIV-1 on pre-cleaned inanimate surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV, HCV and HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, 5 minutes to kill HBV & HCV and all other viruses listed on label, and for 10 minutes to kill all bacteria cited on the label.

Disposal of Infectious Material: Blood and other body fluids must be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

For Use as a Bowl Cleaner/Disinfectant in Toilet Bowls [and Urinals] from Use-Dilution:

1. Pre-clean heavily soiled areas.
2. Empty toilet bowls by forcing water through the trap. Apply Use Solution to exposed surfaces in toilet bowls and urinals.
3. Swab entire surface area especially under the rim.
4. Allow entire surface to remain wet for ten (10) minutes.
5. Flush toilet or urinal and rinse swab applicator thoroughly.

For Use as a Cleaner/Disinfectant in Food Processing Plants:

1. Before using this product in food processing areas, food products and packaging materials must be removed from the room or carefully protected.
2. Apply Use Solution evenly over surface. Be sure to wet all surfaces thoroughly.
3. Allow product to remain on surface for ten (10) minutes.
4. Wipe with clean cloth, sponge or paper towel.
5. For heavily soiled areas, thoroughly clean surface prior to disinfecting.
6. This product must not be used to disinfect utensils, glassware, and dishes.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

For Treatment of Animal Housing Facilities (including Poultry barns):

1. Remove all animals and feeds from areas being treated.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
3. Empty or cover all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Apply fresh Use Solution to floors, walls, cages and other washable hard, non-porous inanimate surfaces. For smaller surfaces, use a trigger spray bottle to spray all surfaces with solution until wet. To disinfect, all surfaces must remain wet for ten (10) minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings and other closed spaces. Do not house animals or re-employ equipment until product has dried.
8. To kill viruses on feed racks, troughs, automatic feeders, fountains and watering appliances scrub with use-solution, let stand five (5) minutes. For disinfection of feed racks, troughs, automatic feeders, fountains and watering appliances scrub with use-solution, let stand ten (10) minutes. Then thoroughly scrub all treated surfaces with soap or detergent and rinse with potable water before reuse.

(Note - When cleaning floors position wet-floor signs around area to be cleaned. Floors will be slippery when wet or contaminated with foreign materials. Promptly clean up spills and foreign materials.)

To Sanitize Non-Food Contact Surfaces: Dilute at 1 oz. - 2 oz. of product per gallon of water (1:64 to 1:128).

1. Pre-clean heavily soiled hard non-porous surfaces.
2. Apply Use Solution until thoroughly wet.
3. Let stand for three (3) minutes.
4. Then wipe (and allow to air dry).
5. Not for use on food contact surfaces or on food preparation areas.

Note - Do not use on glassware, utensils, or dishes.

For Use as a Deodorizer: Dilute at 1 oz. - 2 oz. of product per gallon of water (1:64 to 1:128). Apply to hard, non-porous surfaces. Let stand for three (3) minutes. (Wipe surfaces (and let air dry).)

For Use as a Cleaner/Degreaser: Dilute product at 1/2 oz. - 2 oz. of product per gallon of water (1:64 to 1:256). Apply to hard, non-porous surfaces. Wipe surfaces (and let air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

Do not reuse empty container (unless refilling from a larger container of the same product according to the refilling directions outlined previously). Keep from freezing.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL *Note to reviewer – One or more of the following paragraphs for Container Disposal will be selected, depending on packaging type:*

NONREFILLABLE SEALED CONTAINERS: *Note to reviewer: Several of our packaging options (including ACCUMIX Containers™, Solutions Center™, J-Fill™ Dispensing System, OUTPOST™, Single Solutions™, Command Center™, or RTD™ Dispensing Systems) are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

NONREFILLABLE NON-RIGID CONTAINERS: *Note to reviewer: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers (such as ACCUPACK™ Containers). These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

NONREFILLABLE READY-TO-USE FORMULATIONS: *Note to reviewer: The following text will be used on nonrefillable RTU container labels:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

SMALL NONREFILLABLE CONTAINERS: *Note to reviewer: The following text will be used on rigid, nonrefillable containers small enough to shake (5 gallons or smaller):*

Nonrefillable container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

LARGE NONREFILLABLE CONTAINERS: *Note to reviewer: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):*

Nonrefillable container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for reconditioning, if appropriate.

OR

Nonrefillable container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

REFILLABLE CONTAINERS: *Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name) pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

ENVIRONMENTAL HAZARDS *(for containers of 5 gallons or larger)*

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear chemical splash-proof goggles or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using the toilet.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.
1-XXX-XXX-XXXX**

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

EPA Reg. No. 70627-62

EPA Est. No.

(Lot code letters indicate manufacturing location.)

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PHATO 1:64 DISINFECTANT CLEANER

REFERENCE SHEET

When used as directed, this product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic-resistant bacteria, and *viruses). At a 1:64 dilution (2 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 10 minute contact time, unless otherwise noted, this product kills the following on hard non-porous inanimate surfaces:

Bacteria (Bactericidal Activity):

Pseudomonas aeruginosa, (ATCC 15442)

Salmonella enterica, (ATCC 10708)

formerly known as *Salmonella choleraesuis*

Staphylococcus aureus, (ATCC 6538)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Staphylococcus aureus, (Methicillin Resistant *Staphylococcus aureus* [MRSA]) (ATCC 33591)

Staphylococcus aureus, (Community Associated - Methicillin Resistant *Staphylococcus aureus* [CA-MRSA]) (Clinical Isolate 08005)(Genotype USA400)

Enterococcus faecium, (Resistant to Vancomycin [VRE]) (ATCC 51559)

Staphylococcus aureus, (Community Associated - Methicillin Resistant *Staphylococcus aureus* [CA-MRSA]) (Clinical Isolate 08001) (Genotype USA300)

At a 1:64 dilution (2 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 5 minute contact time, unless otherwise noted, this product kills the following on hard non-porous inanimate surfaces:

***Viruses (*Virucidal Activity):**

*Adenovirus type 8, (ATCC VR-1368, Strain Trim)

*Herpes Simplex Virus Type 2, (VR-734)

*Human Coronavirus, (VR-740)

*Influenza Virus Type A₂ (Hong Kong), (VR-544)

*Norovirus (Feline Calicivirus as the surrogate), (VR-782)

*Parainfluenza Virus Type 3, (VR-93)

*Poliovirus Type 1, (ATCC VR-1000)

*Respiratory Syncytial Virus, (VR-26)

*Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)

*Rotavirus, (Strain WA)

*Vaccinia Virus (smallpox vaccine virus), (ATCC VR-119)

Kills *Hepatitis B Virus (HBV) & *Hepatitis C Virus (HCV) when used as directed on hard, non-porous inanimate surfaces with a 5 minute contact time.

Kills *HIV-1 (Human Immunodeficiency Virus Type 1) (AIDS virus) (HTLV-III_B) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Kills *Influenza A Virus (H1N1) (ATCC VR-1469, Strain A/PR/8/34) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

(*Veterinary Viruses:)

*Avian Influenza Virus A, (H3N2) (ATCC VR-2072)

Sanitizing: When used as a non-food contact sanitizer at a 1:128 dilution (1 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load, this product reduces the following bacteria by 99.9% with a 3 minute contact time on hard non-porous inanimate surfaces:

Staphylococcus aureus (ATCC 6538)

Klebsiella pneumoniae (ATCC 4352)

Escherichia coli (ATCC 11229)

Enterococcus faecalis (ATCC 29212)

Listeria monocytogenes (ATCC 19111)

Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica, (ATCC 10708)

(formerly known as *Salmonella choleraesuis*)

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Bactericidal Stability of Use-Solution - Tests show this product as a disinfectant, when diluted at 1:64 dilution (2 oz. of product per gallon of water) in 200 ppm hard water, in the presence of 5% serum, remains effective against *Staphylococcus aureus*, *Salmonella enterica* (formerly known as *Salmonella choleraesuis*) and *Pseudomonas aeruginosa* for up to 10 (- 90) days in storage as long as the bottle remains sealed. If the use-solution becomes visibly dirty or contaminated, it must be discarded and a fresh product prepared. Always use clean, dry containers when diluting this product. Treated surfaces must remain wet for 10 minutes.

Malodor(s) (Activity) (Odor) (Counteractancy) - reduces odors and odor-causing bacteria on hard, nonporous surfaces, in restroom areas behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors), (when used as directed at a 1:64 dilution (2 oz. of product per gallon of water)), (or) (when used as directed at a 1:64 - 1:128 dilution (1 - 2 oz. per gallon of water)), in the presence of 200 ppm hard water and a 3 minute contact time.

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